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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/900,355	07/06/2001	H. Craig Dees	PHO-122	5998

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COOK, ALEX, McFARRON, MANZO,
CUMMINGS & MEHLER, LTD.
Suite 2850
200 West Adams St.
Chicago, IL 60606

EXAMINER

EPPS FORD, JANET L

ART UNIT	PAPER NUMBER
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1633

DATE MAILED: 02/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary**Application No.**

09/900,355

Applicant(s)

DEES ET AL.

Examiner

Janet L. Epps-Ford

Art Unit

1633

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 November 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,9-11,19 and 27 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,9-11,19 and 27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 1633

DETAILED ACTION

1. Claims 1-2, 9-11, 19 and 27 are currently pending.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Priority

3. Applicants have currently amended the first line of the specification to incorporate wherein the instant application is a continuation-in-part of US application 09/635,276 filed on August 9, 2000 which is a continuation-in-part of US application 09/216,787 filed December 21, 1998. Applicant's claim for priority to the earlier filed application is improper. The instant application was filed after November 29, 2000. For patent applications filed after November 29, 2000, as per 37 CFR § 1.78(a)(1) "In order for an application to claim benefit of a prior-filed application, the prior filed application must be a ***copending nonprovisional application***." Furthermore, as per § 1.78(a)(2)(i)-(ii), reference to the earlier filed application must be made within the later of four months from the actual filing date of the later filed application, or sixteen months from the filing date of the earlier filed application. Application 09/216,787 issued as a US Patent on December 18, 2001. Therefore, Applicant's attempt to claim priority to the earlier filed application in the amendment filed 11/21/2005 is improper. If Applicants consider that this claim for priority was unintentionally delayed, Applicants should have provided a petition to accept an unintentionally delayed claim under 37 CFR 1.78(a)(3)(i)-(iii).

Claim Rejections - 35 USC § 102

4. Claims 1, 9-11, 19 and 27 remain rejected under 35 U.S.C. 102(e) as being anticipated by Dees et al. (US Patent No. 6,331,286, filing date 12-21-1998), for the reasons of record set forth in the prior Office Action.

5. Applicant's arguments filed 11-21-05 have been fully considered but they are not persuasive. Applicants traverse the instant rejection on the grounds that the instant application is a continuation-in-part of US application 09/635,276, which is a continuation in part of 09/216,787, the application from which US 6,33,286 issued from. However, contrary to Applicant's assertions, Applicant's claim for priority to the prior filed application 09/216,787 is improper as per 37 CFR 1.78(a)(1). Therefore, it remains that the instant claims are anticipated over Dees et al. for the reasons set forth in the prior Office Action.

The prior art is applied to the extent that it discloses compositions consisting of halogenated xanthene compounds in aqueous solution. The limitations "injectable chemotherapeutic" and "for chemotherapeutic treatment of diseases of human and animal tissue," are considered intended use limitations. These limitations are not considered to hold any patentable weight since they do not function to result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. See MPEP 2111.02 [R-2].

Dees et al. describe a variety of halogenated xanthene compounds that are generally highly soluble in aqueous solution (see col. 5, lines 1-6).

Art Unit: 1633

Representative halogenated xanthene compounds of Dees et al. include the disodium salt of 4,5,6,7-Tetrabromoerythrosin; see col. 7, Table I. The agents of Dees et al. may be delivered to a target using by controlled agent delivery at, near or into the target, for example by encapsulation, the agent by also be delivered locally by means of injection (see col. 4, lines 35-52).

The halogenated xanthene compounds of Dees et al. may also be delivered in conjunction with a delivery vehicle such as a surfactant, including topical creams, lotions, and liquids for intravenous or parenteral injection (col. 5, lines 44-54).

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 1-2, 9-11, 19, and 27 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. (New Matter).

Applicants have currently amended the instant claims to recite an injectable chemotherapeutic pharmaceutical composition consisting of a halogenated xanthene in aqueous solution, wherein said halogenated xanthene is a compound selected from the group consisting of 4,5,6,7-

Art Unit: 1633

Tetrabromoerythrosin, Monobromoerythrosin, Dibromoerythrosin,
Tribromoerythrosin, Monochloroerythrosin, Dichloroerythrosin,
Trichloroerythrosin, Monofluoroerythrosin, Difluoroerythrosin, Trifluoro-erythrosin,
2', 7'-Dichloro-4, 5,6,7-Tetrafluorofluorescein, 2', 4,5,6,7,7'-Hexafluoro-
fluorescein and 4,5,6,7-Tetrafluorofluorescein, wherein said halogenated
xanthene does not contain a functional derivative at position R¹ or R², and
wherein said pharmaceutical composition is for chemotherapeutic treatment of diseases of human and animal tissue. Applicants have amended the claims to remove the limitation "disodium or dipotassium salt."

In support of their amendment, Applicants stated (on page 7 of the response filed 11/21/05):

The claimed pharmaceutical compositions of the present application are directed to formulations of certain novel highly-halogenated halogenated xanthenes, including 4,5,6,7-Tetrabromoerythrosin, that are adapted for chemotherapeutic use. The specification of the present application makes it clear that such halogenated xanthenes may be in either a non-derivative or a derivative form, as is clear from the following passage:

"[0023] The present invention is directed to new chemotherapeutic medicaments ... wherein a primary active component of such medicaments is a *halogenated xanthene or halogenated xanthene derivative*." Page 5 (emphasis added).

The identity of these forms is determined by the composition of the functionalities at positions R¹ and R², as illustrated by the following from the present application:

"[0027] Selected chemical and physical properties (such as chemical constituents at positions X, Y, and Z and functionalities R¹ and R²) of representative halogenated xanthenes are summarized in attached Table 1." Page 7.

Art Unit: 1633

Additionally, Applicants made reference to Table 1, stating: "Table 1 shows representative examples of these functionalities, including hydrogen atoms (i.e., if the R1 and R2 are both hydrogen atoms, the halogenated xanthene is in its acid form).

Contrary to Applicant's assertions the passages mentioned by Applicant as support of their amendment do not provide specific support for wherein the specific halogenated xanthene compounds recited in the claims do not contain a functional derivative at position R¹ or R². For example: 4,5,6,7-Tetrabromoerythrosin as described in Table 1 of the specification as filed includes wherein this halogenated xanthene compound comprises Na⁺ ions at the R¹ and R² positions, not just hydrogen atoms.

Applicant's amendments to the claims are considered new matter, since the specification as filed does not provide either implicit or explicit support for the newly added amendments to the claimed.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

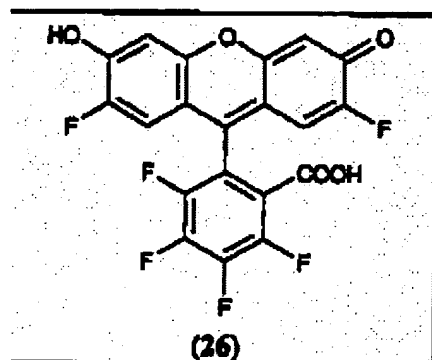
9. Claims 1, 9-11, 19 and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by Gee et al. (WO 97/39064 A1).

Art Unit: 1633

Gee et al. discloses halogenated xanthene dye compositions, including 2',7'-Dichloro-4,5,6,7-Tetrafluorofluorescein, 2',4,5,6,7,7'-Hexafluorofluorescein and 4,5,6,7-Tetrafluorofluorescein (see for example Table 1, page 8). The dye compositions of Gee et al. are preferably in aqueous solution (see page 7, line 4), additionally the dyes are optionally combined with other solutions, including *inter alias*, permeabilization solutions.

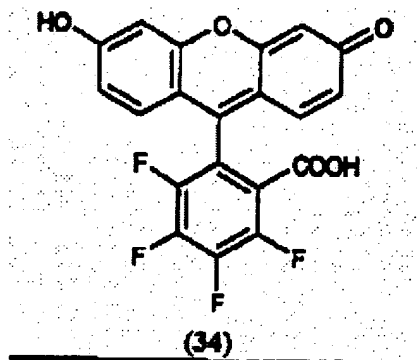
The prior art is applied to the extent that it discloses compositions consisting of halogenated xanthene compounds in aqueous solution. The limitations "injectable chemotherapeutic" and "for chemotherapeutic treatment of diseases of human and animal tissue," are considered intended use limitations. These limitations are not considered to hold any patentable weight since they do not function to result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. See MPEP 2111.02 [R-2].

2',4,5,6,7,7'-hexafluorofluorescein (see page 30, note there is no derivative at the R1 and R2 positions, as defined by Applicants in Figure 1a):

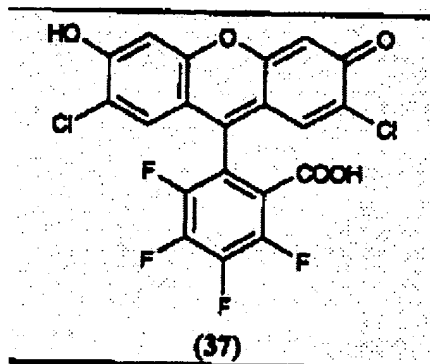


Art Unit: 1633

4,5,6,7-tetrafluorofluorescein (see page 31, note there is no derivative at the R1 and R2 positions, as defined by Applicants in Figure 1a):



2',7'-dichloro-4,5,6,7-tetrafluorofluorescein (see page 31, note there is no derivative at the R1 and R2 positions, as defined by Applicants in Figure 1a):



The dye compositions of Gee et al. in aqueous solution are considered to anticipate Applicant's claimed invention.

Conclusion

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

Art Unit: 1633

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Art Unit: 1633

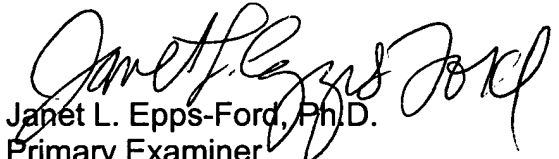
11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L. Epps-Ford, Ph.D. whose telephone number is 571-272-0757. The examiner can normally be reached on Monday-Saturday, Flex Schedule.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dave Nguyen can be reached on (571)272-0731. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.


Janet L. Epps-Ford, Ph.D.
Primary Examiner
Art Unit 1633

JLE